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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,953	03/24/2000	Teresa Leigh Barr	310.18	1956

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EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/534,953		BARR ET AL.	
	Examiner		Art Unit	
		Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The rejection of claims 4,7,8,11,14-16, 28, 30 and 32 of record under 35 U.S.C.112, second paragraph and the nonstatutory double patenting rejection of claims 1-35 are hereby expressly withdrawn in view of Applicants' response. However, upon further consideration, a new ground(s) of rejection is made as follow:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 is indefinite because the claim is incomplete. It is suggested to complete the sentence clearly directed to what's being claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 11-25, 30, 32, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaHann et al. (U.S. Patent No. 4,546,112) in view of Ishiwatari et al. (U.S. Patent No. 6,074,652).

LaHann et al. teach composition formulated in lotions, cream, solutions, gel, comprising capsaicin, emulsifying agents (e.g. sorbitol, glycerin, corn oil), carrier (e.g. fatty alcohols, vegetable and animal oils), and encapsulating agent (e.g. lecithin and derivatives). (abstract, column 3, lines 31-50, column 4, lines 3-14, line 27, line 64, column 5, line 65) for preventing or reducing dermal irritation.

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LaHann et al. do not teach the light scattering element and its particle size and specific amounts of active agents to be utilized and further comprising an additional anti-itch agent including aloe.

Ishiwatarie et al. teach inorganic UV-absorbers including titanium dioxide and zinc oxide and p-amino benzoic acid are compatible with capsaicin. (column 25, lines 65-68, column 26, line 5 and column 30, line 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate titanium dioxide and zinc oxide or p-amino benzoic acid into LaHann et al's composition because Ishiwatari et al. teach titanium dioxide and zinc oxide or p-amino benzoic acid are compatible with capsaicin and because Lahann et al. teach capsaicin is useful for preventing or reducing dermal irritation. One of ordinary skill in the art would have been motivated to incorporate titanium dioxide and zinc oxide or p-amino benzoic acid into LaHann et al's composition to achieve reduction of dermal irritation caused by UV-ray.

Absent any evidence to contrary, there would have been reasonable expectation of success in incorporating the UV-absorber as taught by Ishiwatarie et al. to formulate dermal composition of LaHann et al. to conveniently protect any irritation may caused by UV-ray.

The amounts of active agents to be used, the pharmaceutical forms, e.g., patch, etc; and further combining with other anti-itch agent utilized for same purpose are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

Claims 6-10, 26, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaHann et al. (U.S. Patent No. 4,546, 112) in view of Ishiwatari et al. (U.S. Patent No. 6,074,652) and further in view of Fourman et al. (U.S. Patent No. 4,963,591).

The teachings of LaHann et al. and Ishiwatari et al. are applied as before, with additional teachings as follows.

LaHann et al. disclose capsaicin composition is useful in pain and reduces inflammation.

LaHann et al. do not teach histamine in above composition.

Fourman et al. teach arthritis lotion comprising histamine dihydrochloride, capsaicin and menthol. (column 11-column 13, Formula 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Fourman et al. composition with LaHann et al. formulation as modified by Ishiwatari et al. because each references above are drawn to same technical fields constituted with same active ingredient (capsaicin) and well known additives (e.g. carriers, excipients compatible with capsaicin)), and pertinent to the composition comprising capsaicin use for pain and as a sunscreen which applicant concerns about. MPEP 2141.01(a).

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Claims 2, 27, 29 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over LaHann et al. (U.S. Patent No. 4,546,112) in view of Ishiwatari et al. (U.S. Patent No. 6,074,652) and further in view of McCleane et al. (U.S. Patent No. 6,221,915B1).

The teachings of LaHann et al. and Ishiwatari et al. are applied as before, with additional teachings as follows.

LaHann et al. disclose capsaicin composition is useful in pain and reduces inflammation.

LaHann et al. do not teach benzyl alcohol in above composition.

McCleane teach composition comprising capsaicin and benzyl alcohol useful as an analgesic. (column 9-10, Examples 3 and 5 and column 10 claim 2). McCleane teach that benzyl alcohol is a suitable carrier of capsaicin composition commercially available as AXAIN cream.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate benzyl alcohol into LaHann et al. formulation as modified by Ishiwatari et al. because each references above are drawn to same technical fields constituted with same active ingredient (capsaicin) and well known additives (e.g. carriers, excipients compatible with capsaicin)), and pertinent to the composition comprising capsaicin use for pain and as a sunscreen which applicant concerns about. MPEP 2141.01(a).

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For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Jennifer Kim
Patent Examiner
Art Unit 1617

jmk
May 19, 2003